REMARKS

The necessary change in the specification is made herewith.

The recitations in the claims of the subject matter which in fact is not illustrated in the drawings, is cancelled from the claims. However, not all of the points raised in the Official Action, as to the drawings, require such deletion, because the features are in fact shown in the drawings.

Thus, as to objections 6a and 6b, the lower limit and upper limit are shown in Figure 15. From page 42, lines 5-11, it is clear that the peripheral groove 415 functions as a lower limit as well as a top closure. The valve prosthesis has ribs 418 which slide into axial grooves 414; and after the ribs 418 have entered into the peripheral groove 415 and the valve prosthesis is rotated by a small angle, the ribs 418 will be axially fixed in the peripheral groove 415. Thus, a lower limit and an upper limit are shown in the drawings.

As to objection 6c, see Figure 22, concerning the bottom stop 488, and page 47, line 33. This bottom stop is an inwardly projecting rib.

As to objection 6d, the snap-fit lips are in fact shown in Figure 22, wherein the arms 482 function as snap-fit lips. See page 47, lines 25-30. Line 30 specifically mentions the snap action. However, the screw ring and snap-fit ring are deleted without disclaimer, because they are not illustrated.

As to objection 6f, see Figure 18. The outside 449 of the tubular element is clearly shown to be concave.

The alternative arrangements referred to in objections 9g and 9i have been deleted from their respective claims and now are separately claimed in new dependent claims 120, 121, respectively. These new claims read on the elected embodiment.

As to the claims, note that claims 72 and 91 are now combined, so that the basic claim is directed to an assembly of a prosthesis fixing device and a valve prosthesis.

Thus, we no longer seek to claim e.g. stents.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as anticipated by SHILEY or MARIN et al. These applied references and the patentable distinctions of the claims as now presented, will be separately discussed as follows:

Like the present invention, SHILEY relates to a prosthesis fixing device. The SHILEY device is intended for fixing a heart valve prosthesis inside the heart.

The SHILEY device is quite well summarized in its abstract. The SHILEY device comprises:

- an inner ring 12 carrying a heart valve (of the check valve type);
- an outer ring 11 inside which the inner ring 12 is rotatebly mounted; and
- a series of spaced wires 13 confined between the rings.

Referring to Figure 5, the wires, called wire suture pins 13, lie initially in retracted condition:

- with their length (called body portions 50 in column 7, line 26) essentially in between the rings and extending in the circumferential direction of the rings 11, 12;
- with their free ends 49 being disposed freely in radial openings 35 in the outer ring 11 and facing in radially outward direction;
- with their other ends 43 secured in apertures 41 formed in the inner ring 12 (see column 7, lines 19-23).

Referring to column 7, lines 57-61 and Figure 6, rotating the inner ring 12 with respect to the outer ring 11 brings the wire suture pins 13 to their fully expanded condition at which the pins have been curled back on themselves.

Now comparing SHILEY with claim 72, the following is observed:

SHILEY does not disclose arms and pins which, in the 'insertion' position, are located essentially inside the tubular element.

- Claim 72 requires (see lines 10-12) that *the arm*, carrying the pin, *is attached by one end to the tubular element*.

  o Assuming that the body portions 50 of SHILEY constitutes an arm of claim 72, means that the inner ring 12 of SHILEY constitutes the tubular element of claim 72. This is because the body portions 50 of SHILEY are secured

to the inner ring (see column 7, lines 19-23) with their ends 43 like the arms of claim 72 are attached to the tubular element. The other ends of the body portions of SHILEY are free.

- Claim 72 requires further (see lines 14-18) *wherein the arms and pins are movable, ……, from an insertion position, in which they are essentially located inside the tubular element, into a fixing position in which at least the pins, viewed in the radial direction, project outside the tubular element.*

  o Taking into account that the inner ring 12 of SHILEY constitutes the tubular element of claim 72 in case one assumes that the body portions 50 of SHILEY constitute the arms of claim 72, the above underlined requirement of lines 14-18 of claim 72 is novel over SHILEY.

  o This because, in the retracted condition of SHILEY (comparable with the insertion position of claim 72), the body portions 50 of the SHILEY pins 13 lie entirely outside the inner ring 12, instead of being located essentially inside the inner ring.

SHILEY does not disclose arms and pins that can swing neither does it disclose a bend line around which any swinging takes place.

- Claim 72 requires (see lines 14-15) that *"the arms and pins are movable by swinging about the bend line"* .

o movable by swinging means that the movement is a swivel/hinge action around an axis;

o In SHILEY there is no such movement, neither is their any axis around which a swivel takes place.

o In SHILEY there is a continuously progressing bending process when the suture pins 13 go from their retracted condition to the extended condition. During this bending process the end parts of the pins are transformed from essentially straight wires into strongly curved circular wires. During this bending process the place where the bending takes, momentary, place shifts continuously from the free end 49 of the pin 13, along the body portion 50 of the pin 13, in the direction of the fixed end 41 of the pin 13.

SHILEY does not disclose a bend line around which the arms can swing and via which the arm is attached to the tubular element.

- Claim 72 requires (see line 10-13) that "*each pin is arranged on an arm which, via a bend line, is attached by one end to the tubular element in a manner which permits swinging around said bend line*".

o One might say that in SHILEY the body portions 50 of the suture pins 13 are connected via a bending line to the inner ring 12, because the transition between the wire ends 43 and the tangentially extending body portions 50 is a

bend. However, in SHILEY the body portions 50 cannot swing around this bend because the parts of body portions adjacent the bend will always be constrained to lie between the inner ring 12 and outer ring 11.

Disadvantages of the SHILEY construction

- Due to the two rings 11, 12 and suture wires 13 in between them, the SHILEY construction is relatively thick in radial direction. As one can measure from SHILEY's Figure 5, the outer diameter is about 60 mm and the inner diameter is about 37 mm. This means that about 40% of the cross section of the artery at the location of the heart valve will be obstructed by the SHILEY construction. The SHILEY construction thus influences the blood flow considerable, which is disadvantageous. Although the radial thickness might be reduced a little, the SHILEY construction does not allow overcoming this disadvantage properly.

- The SHILEY device is not functioning reliably. In case only one of the suture pins is obstructed during the transformation from the retracted condition to the extended condition, this is sufficient to impede further rotation of the inner ring and outer ring with respect to each other. The consequence of this is that not only the one obstructed suture pin but all suture pins 13 cannot reach their extended condition. Additional problem of this is that one will not notice this easily as the suture pins 13 are hidden between the inner and outer ring or inside surrounding tissue. This can cause all kinds of heart failure. The fixation

of the SHILEY device in the human body as well as its functioning are thus not reliable. The SHILEY construction does not allow solving this problem.

- The assembling of the SHILEY device is relatively complicated. Inner ring and outer ring must be placed inside each other. Referring to column 7, lines 34-56, the slots 35 in the outer ring 11 and the apertures 41 in the inner ring must be aligned to coincide with each other in order to be able to insert the series of wires 13. Subsequently the inner ring 12 and outer ring 11 must be rotated about 30° in order to reach the configuration of figure 5. Especially the aligning and placing of the wires requires special care making the assembling complicated.

- In case the rings 11 and 12 might rotate with respect to each other during use in implanted condition, the anchoring of the pins 13 might be lost because the wires might be retracted to inside the outer ring.

MARIN does not disclose an assembly comprising a valve prosthesis.

- MARIN relates to an intraluminal stent. The (new amended) main claim 72 however relates to a different field of art. It does not relate to a stent but to a heart valve prosthesis.

MARIN does not teach pins having pointed ends facing outwards when in the insertion position.

- The MARIN device has a tubular design. Further, the MARIN device can be transformed from an unexpanded condition (Figure 1) to an expanded condition (Figure 2). Further, the MARIN device has straight barbs 18 with pointed ends. In the unexpanded condition those barbs lie flat in the surface of the tubular member (see column 3, lines 3-5) from which the stent has been made cut. In this unexpanded condition, the pointed ends of the barbs 18 extend in axial direction. Assuming that the barbs constitute arms, MARIN has no pins, which in the unexpanded condition (insertion position) face in radial outward direction.

Disadvantages of the MARIN stent

- Taking into account that the MARIN device is a stent it is not suitable for fixing a valve prosthesis in the human/animal body.

- Taking into account that in the MARIN stent the barbs 18 will, upon expansion of the tubular member, deploy to a slanting position (in which the barbs are still straight) the anchoring in the surrounding wall tissue will not be reliable, at least not reliable enough for fixing a heart prosthesis. This because a heart prosthesis will, in use, experience axial forces in both directions. The axial direction of this force depends from and changes with the phase of the heart rhythm.

- In the MARIN device, all arms will stop with further deployment when one arm is obstructed. This because then the tubular member is obstructed from further deployment.

ADVANTAGES OF THE INVENTION

Claim 72 (in combination with claim 91)

- The prosthesis fixing device according to the invention can (contrary to SHILEY) be designed very thin. The tubular element with arms can be cut from a tubular sheet.

- In case one of the arms or pins might be obstructed from swinging (completely) to the fixing position, the other arms and pins are not obstructed. Both in SHILEY and in MARIN, obstruction of one arm or pin means that all other arms and pins are obstructed as well because those arms and pins cannot moves independently from each other.

- Reliable fixation of the prosthesis fixing device inside the peripheral wall part of the circulatory system can be checked easily. The anchoring of each pin can be verified by checking the position of the arm. In case the arm extends parallel to the tubular element, the anchoring will be as intended. In case the swing of the arms is achieved by pushing the arms in outward direction by inserting the valve prosthesis inside the tubular element, the check will be that the valve prosthesis fits correctly. If this is the case, one knows that all arms extend parallel to the tubular element.

- Because in implanted condition the valve prosthesis is placed inside the tubular element, the arms and consequently also the pins will be prevented from swinging back in the direction of their insertion position. This prevents disengagement of the

anchoring during use after implantation. Both in MARIN and in SHILEY disengagement of the anchoring is possible.

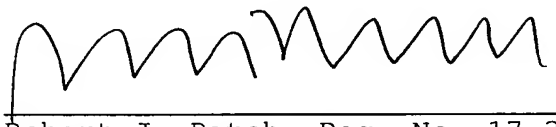
Claim 72 (combined with claim 91) thus is novel as well as inventive.

As the claims as now constituted clearly bring out these distinctions with ample particularity, it is believed that they are all patentable, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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